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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,306	04/08/2008	Lawrence Solomon	SLP-034	2575

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ACCU-BREAK TECHNOLOGIES, INC.
1000 SOUTH PINE ISLAND ROAD
SUITE 230
PLANTATION, FL 33324

EXAMINER	
BARHAM, BETHANY P	
ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,306	SOLOMON ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *6,11, 13-14,24 and 27-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,12,15-23,25,26 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/07, 2/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of IDS filed on 05/18/07 and 02/12/08 is acknowledged. Receipt of Applicant's Response filed on 10/31/09 is also acknowledged. Claims 1-44 are pending.

Election/Restrictions

Claims 27-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/31/09. Further, due to election of species by applicant of (a) "said tablet includes two or more segments and all segments contain a pharmacologically effective dose of a drug or drugs contain the same drug (or combination of drugs at the same ratio)" of instant claim 1, thus claims 6, 11-14 and 24 are also withdrawn from examination since they do not claim the same drug in the segments. Claims 1-5, 7-10, 12, 15-23, 25-26 and 44 will be examined in the instant application. The requirement is still deemed proper and is therefore made FINAL.

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-10, 12, 15-23, 25-26 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7,329,418. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

Claims 1-5, 7-10, 12, 15-23, 25-26 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 19 of copending application 10/598367. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and

all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,258,027 ('027).

The instant claims are drawn to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

- '027 teaches a multi-fractionable tablet structure configured as a unitary dosage while having readily severable sub-dosage units and score markings readily permitting accurate equal bisectional or trisectional fracture as desired for patient consumption (abstract, Figs. A-Y). '027 teaches that the tablets contain one or more active ingredients (col. 6, lines 41-43) (meeting the limitations of claim 1).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 3,336,200 ('200).

- '200 teaches a unitary dosage form with a plurality of separable sections joined to each other (col. 1, lines 11-22, Figs. 1-3). '200 teaches 1-4 segments containing therapeutic agents such as phenobarbital for immediate release dosages (Example 2) (meeting the limitations of claim 1).

Claims 1-5, 7-10, 12, 15-17, 19-20, 22-23 and 44 is rejected under 35 U.S.C. 102(b) as being anticipated by US 6,183,778 ('778) (as cited in Applicant's IDS).

- '778 teaches a multi-layered tablet containing a layer with one or more drugs for immediate release, an intermediate layer with a drug for immediate release and another layer with a drug wherein the drug in the second layer is included in an amount less than the drug in the first layer (abstract, Fig. And claims 1 and 3). Drugs of '778 include pain killers such as ibuprofen and cardiovascular med such a dilitiazem, etc (col. 5, lines 9-29) (meeting the limitations of claims 1-3 and 44).
- '778 teaches different heights of the layers (fig. 1) and horizontal marks (fig. 1) (meeting the limitations of instant claims 4-5).
- '778 teaches that the intermediate layer does not contain a pharmaceutical active (claim 3) and that the drugs in the first and the second layer are equal to each other (col. 3, lines 13-19) (meeting the limitations of instant claims 7-10, 16-17 and 23).

- '778 teaches that the three distinct layers have a specific geometric shape and as shown in Fig 1 have a visible indicia/mark on the second layer layers (claim 1) (meeting the limitations of instant claims 12, 15, 19-20 and 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-10, 12, 15-23, 25-26 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,258,027 ('027) and US 3,336,200 ('200) in view of US 6,183,778 ('778).

- '027 and '200 are taught above and teach a drug containing unitary dosage form with a plurality of separable sections joined to each other (abstracts, Figs, claims) (according to the limitations of instant claim 1).
- '027 teaches that the multi-fractionable tablet can be specially marked with a logo or colored to reflect a different dosage units being consumed (col. 6, lines 48-50) (meeting the limitations of instant claims 12, 18-25). Further as shown in Figs. I-O and U-Y the second segment has a mark located in the middle of the tablet (meeting the limitations of instant claim 26).
- '027 and '200 do not teach a lower concentration of drug in the second segment.

- '778 is taught above and teaches a multi-layered tablet containing a layer with one or more drugs for immediate release, an intermediate layer with a drug for immediate release and another layer with a drug wherein the drug in the second layer is included in an amount less than the drug in the first layer (abstract, Fig. And claims 1 and 3). Drugs of '778 include pain killers such as ibuprofen and cardiovascular med such a dilitiazem, etc (col. 5, lines 9-29) (meeting the limitations of claims 1-3 and 44).
- '778 teaches different heights of the layers (fig. 1) and horizontal marks (fig. 1) (meeting the limitations of instant claims 4-5).
- '778 teaches that the intermediate layer does not contain a pharmaceutical active (claim 3) and that the drugs in the first and the second layer are equal to each other (col. 3, lines 13-19) (meeting the limitations of instant claims 7-10, 16-17 and 23).
- '778 teaches that the three distinct layers have a specific geometric shape and as shown in Fig 1 have a visible indicia/mark on the second layer layers (claim 1) (meeting the limitations of instant claims 12, 15, 19-20 and 22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '027 and '200 with '778. A skilled artisan desiring to make the known product (ie segmented dosage form) of '027 and '200 with an intermediate or second segment with less drug concentration in it would look to '778 for how to formulate such a segment with predictable results. The combination of a known product

'027 and '200 with a known technique of formulating a layer with less drug in it as taught by '778 is within the purview of the skilled artisan and would yield predictable results.

Cited As Interest

US 4,824,677 teaches a divisible tablet for release of an active with a breakable connecting structure with 2-3 segments (abstract, Figs. 1, 6, 8 and 10).

US 4,353,887 teaches a divisible tablet for release of an active (abstract, Figs. 1-3).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615